

## REMARKS

All outstanding requirements will now be addressed in the order they appear in the Office Action mailed November 17, 2008.

### *Claim Rejections under 35 USC § 112*

1. Claims 1-13 and 24-32 stand rejected under 35 USC 112, first paragraph, as allegedly failing to comply with the written description requirement. Specifically, the Examiner alleges there is no support in the specification for the recitation of “a solvent selected from the group consisting of C<sub>2</sub>-C<sub>8</sub> aliphatic esters.”

Applicants respectfully disagree and submit that support can be inferred by a skilled artisan from the Substitute Specification as originally filed, e.g., from paragraphs [0024], [0034], [0104], [0107], [0109], [0111], [0113], [0115].

Nevertheless, solely to expedite prosecution of allowable subject matter, Applicants have amended claims 1 and 8 to include the limitation “esters formed from a C<sub>1</sub>-C<sub>4</sub> aliphatic alcohol and formic acid, acetic acid, or propionic acid,” for which literal support can be found in paragraph [0034] of the Substitute Specification as originally filed, which reads in relevant part as follows:

*In this case, the necessary condition of the selective crystallization of α-crystal form of Imatinib monomesylate is, upon the completion of the acid addition reaction, adding to the reaction mixture of the ester of lower carboxylic acid and C<sub>1</sub>-C<sub>4</sub> aliphatic alcohol (ester-type solvent). The preferred ester-type solvents could be alkyl esters of formic acid, acetic acid and propionic acid, especially ethyl acetate.*

In light of Applicants’ amendment to claim 1 and 8, withdrawal of the written description rejection is respectfully requested.

2. Claims 1-13 and 24-32 stand rejected under 35 U.S.C. 112, second paragraph, as being allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

With respect to claims 1 and 8, the Examiner alleges that in the new recitation of “a solvent selected from the group consisting of C2-C8 aliphatic esters,” it is not possible to determine the structure or identity of C2-C8 aliphatic esters.”

Applicants respectfully disagree and submit that a skilled artisan would know what is meant by C<sub>2</sub>-C<sub>8</sub> aliphatic esters, i.e., that in the absence of additional definitions, both the count of the carbon atoms (2-8) and the type of structure (aliphatic) would necessarily apply to the entire ester molecule. However, this rejection is now moot in light of Applicant’s amendments to claims 1 and 8.

3. With respect to claims 11, 26, and 30, the Examiner alleges that “unless Applicants can establish that the alpha and beta forms have different IR, the reference to IR is meaningless.”

Applicants respectfully submit that the difference in IR spectra between the alpha and beta forms is well-established in the specification. Particularly, Applicants refer the Examiner to Fig. 1, which shows an overlay of FT-IR spectra of imatinib monomesylate form alpha and imatinib monomesylate form beta, and to paragraphs [0056]-[0058] and Table 1 of the Substitute Specification as originally filed, which describe with particularity the characteristic IR resonances of the two forms. As stated in paragraph [0056]:

*The IR spectrum of the  $\alpha$ -crystal form, measured using a KBr pellets technique, is essentially different from that of the  $\beta$ -crystal form within the whole range of the spectrum (4,000 - 400 cm<sup>-1</sup>).*

Applicants submit that the absence of the beta form could be most easily ascertained by determining whether the resonance at 1596 cm<sup>-1</sup> is absent. That resonance is sufficiently far away from the  $\alpha$ -crystal resonances at 1660 cm<sup>-1</sup> and 1572 cm<sup>-1</sup> so as not to present a difficulty with respect to overlap of resonances, particularly in light of the fact that the resolution of present-day IR spectrometers is better than 0.5 cm<sup>-1</sup> and the wavenumber precision is better than  $\pm 0.01$  cm<sup>-1</sup>.

Accordingly, Applicants respectfully request withdrawal of the indefiniteness rejection with respect to claims 11, 26, and 30.

4. With respect to claim 32, the Examiner alleges that “the phrase ‘peaks of relative intensity over 20%’ is indefinite, because the standard against which intensity is determined is not identified and the basis for the percentage (e.g., area under the peak, peak height, etc.) is not defined.”

Without acquiescing in the rejection, solely to expedite prosecution of allowable subject matter, Applicants have amended claim 32 as suggested by the Examiner. Applicants submit that the basis for this amendment is found in Figure 3 and Table 3, which clearly show that the relative intensity of the main peaks listed in the claim is greater than 20% with respect to that of the most intense peak, i.e., the peak at 2 $\theta$  angle of approximately 18.6°, the intensity being expressed as cps (counts of photons per second) and corresponding to the height of the peaks at the particular 2 $\theta$  angle.

In light of the arguments and amendments presented above, Applicants respectfully request reconsideration and withdrawal of all 35 USC 112 rejections.

***Finality of the Office Action***

The Examiner has marked the Office action of November 17, 2008 FINAL. However, in that Office action, the Examiner has introduced a new ground of

rejection that was not necessitated by Applicants' amendments of the claims. Specifically, the Examiner rejected claim 32 for the first time in the Office action of November 17, 2008 basing the rejection on the phrase "peaks of relative intensity of 20%," even though that phrase was present in the claims as originally filed and Applicants did not amend claim 32 in the amendment dated August 30, 2008. Accordingly, Applicants respectfully submit that the finality of the Office action of November 17, 2008 is premature. See, MPEP §706.07(a).

Therefore, Applicants respectfully request reconsideration and withdrawal of the finality of the rejection. Applicants reserve the right to petition from the finality of the Office action under 37 CFR 1.181.

#### ***CONCLUSION***

In view of the foregoing amendments and remarks, Applicants submit that the pending claims are in condition for allowance. Early and favorable reconsideration is respectfully solicited. Should an extension of time be required, Applicants hereby petition for same and request that the extension fee and any other fee required for timely consideration of this submission be charged to **Deposit Account No. 503182**.

Customer Number: **33,794**

Respectfully Submitted,

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